

Response dated June 9, 2005  
Reply to Office Action dated February 9, 2005

Application No. 10/052,077

### **REMARKS**

Claims 1-12 and 14-35 are pending with this paper. Claims 1-12 and 14-33 are rejected under 35 U.S.C. § 103(a) as being unpatentable in light of U.S. Patent No. 4,604,089 to Santangelo *et al.* ("Santangelo") in view of U.S. Patent No. 4,447,224 to DeCant, Jr. *et al.* ("DeCant"). Claims 34-35 are new. No new matter has been introduced into the application. Applicants are respectfully responding to the Final Office Action dated February 9, 2005 and the Advisory Office Action dated May 26, 2005. The Applicants note that some of the arguments presented below have been presented in the Amendment and Response to the Final Office Action filed May 3, 2005. Applicants have included additional remarks directly responsive to the Final Office Action and Advisory Office Action.

### **New Claims**

Claims 34-35 are new. Support is at least found in Figures 1-4, thus no new matter has been added. Applicants respectfully submit that claims 34-35 are in condition for allowance and respectfully request notification of same.

### **Rejection under 35 U.S.C. § 103(a)**

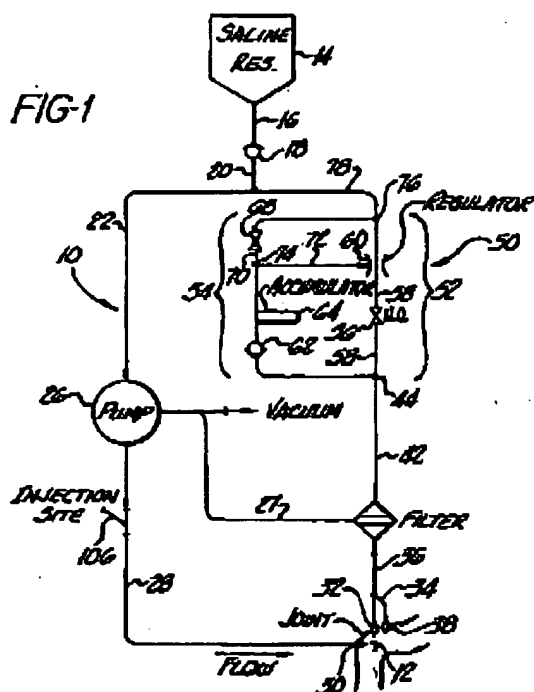
Independent claims 1, 6, 11, 14 and 21 were rejected under 35 U.S.C § 103(a) as being unpatentable over Santangelo in view of DeCant. These pending claims are directed to a flow control device that is configured to be implanted within a patient and the flow control device is used to control flow from an implanted pump.

As previously discussed in a prior response, the Applicants respectfully submit that there is no motivation to combine the Santangelo reference with the DeCant reference and that there would be no expectation of success in combining these two references.

FIG. 1 of Santangelo is provided below:

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Santangelo explains that the pressure accumulation branch 54 and the flow restriction branch 52 are used to provide a pressure regulation circuit 50. (Santangelo, C. 4, L. 11-29). The purpose of the pressure regulation circuit 50 is to control the pressure experienced by the joint 12. (Santangelo, C. 4, L. 42-56). As previously noted, the method of flow control used by Santangelo would be unsafe for use in controlling flow from an implanted pump and, therefore, Santangelo cannot fairly be considered analogous art. With respect to the Office Actions comments that the preamble is generally not limiting, the Applicants respectfully submit that the primary reference used to support a rejection must at least be capable of meeting the recited purpose of the claim. See MPEP § 2111.02. The apparatus disclosed in Santangelo and the method it teaches clearly would not be safe to be implanted within a patient and therefore a device according to Santangelo could not be implanted within a patient to control an implantable pump. Accordingly, Applicants respectfully submit Santangelo fails to support an obviousness-type rejection. See MPEP 706.02(j) ("To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify

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the reference or to combine reference teachings. Second, there must be a reasonable expectation of success.).

In other words, Applicants respectfully submit that attempting to seal an inlet catheter and an outlet catheter to tissue within a patient and then enclosing the sealed tissue within a patient and using a pressure restrictor in the outlet catheter to control the flow provided through the inlet catheter, as taught by Santangelo, would be extremely dangerous to the patient. For example, if a leak formed around either the inlet or the outlet catheter, the method of Santangelo would cease to control the flow of the drug and the patient would receive an overdose of the drug, which could possibly kill the patient. Applicants respectfully assert that such a device would not be implanted within a patient and Applicants respectfully submit that the Final Office Action has not provided a persuasive response to this assertion. If the Examiner disagrees with this point, the Applicant respectfully requests that the Examiner provide an example illustrating the use of such a method within a patient. Otherwise, Applicants respectfully submit that Santangelo fails to support a *prima facie* case of obviousness because there would be no motivation to combine components of DeCant with Santangelo (which is plainly unsuitable to be implanted within a patient) to form a flow control device for an implantable pump. Accordingly, for at least this reason it is respectfully submitted that the combination of Santangelo and DeCant fails to support a *prima facie* case of obviousness.

In addition, Santangelo discloses the use of a reservoir that may be a saline bag hung on a stand. (Santangelo, C. 3, L. 30-35). No other disclosure of a reservoir is provided in Santangelo. Such a reservoir is clearly unsuitable for implanting within a patient and a saline bag is not configured to contain a pressurized supply of a drug.

Independent claims 1, 6 and 11 recite "a reservoir for containing a pressurized supply of drug." As noted above, Santangelo fails to disclose such a reservoir. As previously noted, the reservoir of DeCant would not work with the flow control method of Santangelo. Thus, DeCant cannot correct this deficiency. Therefore, the combination of Santangelo and DeCant does not disclose all the limitations of claim 1, 6 and 11. As not all the limitations of claims 1, 6 and 11 are disclosed, suggested or taught by Santangelo and DeCant, the references of record fail to support a *prima facie* case of obviousness for claims 1, 6 and 11 for this additional reason.

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Therefore, it is respectfully submitted that the combination of Santangelo and DeCant fails to support a *prima facie* case of obviousness for the pending independent claims 1, 6, 11, 14 and 21. All remaining pending claims depend from one of these pending claims, thus, for at least the reasons discussed above the dependent claims are also nonobvious in view of the combination of Santangelo and DeCant. Accordingly, withdrawal of this ground of rejection is requested.

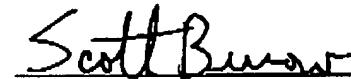
### CONCLUSION

Applicant respectfully submits that the instant application is in condition for allowance. Should the Examiner believe that a conversation with Applicant's representative would be useful in the prosecution of this case, the Examiner is invited and encouraged to call Applicant's representative.

Respectfully submitted,

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By:



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